

**INFORMATION SHEET FOR PARTICIPANTS**

*Ethical Clearance Reference Number: LRS-18/19-13264*

**Investigating the effects of cardio and non-cardio exercise on adults with Attention Deficit Hyperactivity Disorder (ADHD)**

In this research study we will use information from you. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules. At the end of the study we will save some of the data to check the results and a fully anonymised dataset will be published if a suitable online repository is found. We will make sure no-one can work out who you are from the reports we write.

The information pack tells you more about this.

**What is the purpose of the study?**

Attention Deficit Hyperactivity Disorder (ADHD) affects around 3% of adults and is associated with reduced attention, high levels of impulsivity, hyperactivity and altered reward learning. At present adult ADHD is normally treated with psychostimulant medications (e.g. Ritalin or Adderall) but there are concerns about side effects, abuse potential and they do not work for everyone. It is therefore important to consider alternative approaches. Preliminary research on children suggests exercise may be a suitable intervention. The purpose of the study is to assess whether two forms of exercise (cycling on an exercise bike or yoga) are effective in reducing the symptoms of ADHD in adults, both alone and in combination with psychostimulant drug treatment.

**Why have I been invited to take part?**

You are being invited to participate in this study because you are aged 18-35 years and are free from any physical, neurological or psychiatric conditions and learning disorders/disabilities. You will also fall into one of the three categories:

1. No current or previous diagnosis of ADHD
2. Current diagnosis of ADHD but not currently receiving any drug treatment for the condition (and have not done so for 6 months)
3. Current diagnosis of ADHD and currently receiving drug treatment for the condition.

To participate in this study, you must also be fit to exercise. To confirm this, we will ask you to complete a brief online screening survey. Fitness will also be confirmed on arrival for testing using a blood pressure check.

**What will happen if I take part?**

If you choose to take part in the study, you will be asked to first complete a brief online screening survey (<15 mins). The first stage consists of a short 7-question survey to assess your fitness to participate. If your results indicate you are fit to participate you will be asked to answer further questions including basic demographic information (e.g. age, gender) and some questions about your typical exercise habits. The final part of the screening survey that all participants will complete will include a question asking you about any current ADHD diagnosis and the Adult ADHD Self-Report Scale, a short survey assessing ADHD symptomology. For those who report a diagnosis of ADHD, details of treatment (e.g. dose, drug) will be required. Finally, you will be asked to provide an email address to allow researchers to contact you to arrange a time to visit the laboratory to participate in the study.

Those who complete the screening survey will be contacted to arrange a convenient time to attend the laboratory. On arrival, the researcher will take a measure of your blood pressure to confirm fitness to exercise. Participants with ADHD will also be asked to complete a brief medication adherence survey on paper. All participants will be asked to wear a small activity monitoring device, similar to the common ‘fit bit’ watches on either their wrist or ankle during testing. Testing will be in two phases - before and after exercise – with the same computerised tests completed in both phases and aim to measure attention, impulsivity and reward learning. Brief descriptions of the tests are given below:

1. Test of attention – you will be asked to press a letter on a keyboard to respond to a target stimulus whilst inhibiting responses to non-target stimulus.
2. Tests of impulsivity – two specific tests will be used to measure impulsivity. In the first test you will be asked to make choices, using keyboard presses, between hypothetical rewards now or at a point in the future for several different delays e.g. 1 week, 2 weeks, 1 month, 3 months, 6 months and 1 year. In the second test you will be shown 4 decks of cards (labelled A, B, C, and D) and asked to choose 100 times from the decks with two decks giving greater gains and losses.
3. Test of reward learning – you will be presented with one of two stimuli and asked to make a keyboard response. Shortly after the initial stimulus is presented a second stimulus will be shown, for which there are two options, one symbolic of a reward. During this task we will track your eye movements.

After completion of these tasks you will be asked to either cycle with moderate intensity on an exercise bike for 10 mins or follow an instructional yoga video for the same period. Following this, the above tasks will be completed. In total testing should take around 2 hours and will take place in the Psychology Department at King’s College London.

**Do I have to take part?**

Participation is completely voluntary. You should only take part if you want to and choosing not to take part will not disadvantage you in anyway. Once you have read the information sheet, please contact us if you have any questions that will help you make a decision about taking part. If you decide to take part, we will ask you to complete an online consent form before beginning the online screening survey.

**What happens if a participant, who has given informed consent, loses capacity to consent during the study?**

Considering that the study involves a single laboratory visit, it is not practicable for the research team to monitor capacity and continued capacity will be assumed, unless specifically contacted by a former participant or their caregiver.

**Incentives**

Participants who attend and complete the laboratory for testing will receive a £22 amazon voucher as a ‘thank you’ for participating.

**What are the possible risks of taking part?**

Only participants who are deemed physical fit enough to participate will be eligible to take part and therefore, we don’t anticipate any specific risks in taking part, however, we will be asking about symptoms of ADHD and use of medication, where appropriate. If you find talking about these topics distressing, you may prefer not to take part in this study.

**What are the possible benefits of taking part?**

The data collected will provide valuable information about the effectiveness of exercise in treating ADHD and therefore has the potential to be beneficial to patients with the condition in the future. There are no direct benefits to you for participating in this study, although those who attend and complete laboratory testing will receive an amazon voucher as a ‘thank you’, as outlined above.

**Data handling and confidentiality**

Your data will be processed in accordance with the General Data Protection Regulation (GDPR, 2018). If you would like more general information on this please visit the link below:

<https://www.kcl.ac.uk/research/support/research-ethics/kings-college-london-statement-on-use-of-personal-data-in-research>

On this research project we will comply with the following:

* On receipt of screening survey data, email addresses will be removed from the dataset and replaced with a participant ID, meaning screening data will be stored anonymously. This ID will then be used for all data collected. Email addresses will be stored separately to allow participants to be contacted for booking in testing times. During the study all data will be stored on secure university servers, accessible to only the research team.
* After the study has ended, personal data will be disposed, except for consent forms, which will be stored for 4 years after the end of the study. Consent forms will be stored on a password-protected, restricted-access cloud service and in a locked cupboard at Addison House, Guy’s Campus. Only the immediate research team will have access to these consent forms. In line with King’s data retention policy, they will be destroyed after 4 years.
* At the end of the study, email addresses will be deleted, and fully anonymised data will be stored on the university servers for up to five years after publication of the work, accessible only to the researchers. Should a suitable online data repository be available, a full set of anonymised data will be placed on the platform to allow future accessibility.
* Participants will not be identifiable from any outputs of the project (e.g. report).

**How will we use information about you?**

We will need to use information from you for this research project.

This information will include your name and e-mail address. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results and we may publish a fully anonymised dataset on an online repository. We will write our reports in a way that no-one can work out that you took part in the study.

**What are your choices about how your information is used?**

You can stop being part of the study at any time, without giving a reason. Withdrawing from the study will not affect you in any way.

You are able to withdraw your data up to three months after completion of testing, after which your anonymised data will have been included in analyses and interim reports.If you choose to withdraw from the study we will not retain the information you have given thus far.

We need to manage your records in specific ways for the research to be reliable. This means that we won’t be able to let you see or change the data we hold about you.

**Data Protection Statement**

The data controller for this project will be King’s College London (KCL) and South London and Maudsley NHS Foundation Trust (SLaM). The University will process your personal data for the purpose of the research outlined above. The legal basis for processing your personal data for research purposes under GDPR is a ‘task in the public interest’ You can provide your consent for the use of your personal data in this study by completing the consent form that has been provided to you.

You have the right to access information held about you. Your right of access can be exercised in accordance with the General Data Protection Regulation. You also have other rights including rights of correction, erasure, objection, and data portability. Questions, comments and requests about your personal data can also be sent to the King’s College London Data Protection Officer Mr Albert Chan [info-compliance@kcl.ac.uk](file:///\\kclad.ds.kcl.ac.uk\anywhere\UserData\PSStore02\k1217397\My%20Documents\2018\info-compliance@kcl.ac.uk). If you wish to lodge a complaint with the Information Commissioner’s Office, please visit [www.ico.org.uk](http://www.ico.org.uk).

**How is the project being funded?**

This study is being funded by Rosetrees Trust. Details of this trust can be found here: <https://rosetreestrust.co.uk/>

**What will happen to the results of the study?**

The results of the study will be summarised in several different outputs including student dissertations, funder reports and peer-reviewed journals and presentations. You are welcome to have a copy of any final report or publication. Please tell the researchers if you would like this. As indicated above fully anonymised dataset may be placed on a suitable public data repository.

**Where can you find out more about how your information is used?**

You can find out more about how we use your information:

* at [www.hra.nhs.uk/information-about-patients/](http://www.hra.nhs.uk/information-about-patients/)
* at www.hra.nhs.uk/patientdataandresearch
* by asking one of the research team
* by sending an email to Larisa.Dinu@kcl.ac.uk or Eleanor.Dommet@kcl.ac.uk

**Who has reviewed the study?**

The study has been reviewed by the North of Scotland Ethics Committee 1.

**Who should I contact for further information?**

If you have any questions or require more information about this study, please contact the Research Assistant using the following contact details:

**Miss Larisa Dinu**

Department of Psychology, Institute of Psychiatry, Psychology and Neuroscience

2.04 Addison House

Guy’s Campus, King’s College London

Email: [Larisa.Dinu@kcl.ac.uk](mailto:Larisa.Dinu@kcl.ac.uk)

**What if I have further questions, or if something goes wrong?**

Should you have further queries about the study, please contact the Principal Investigator of the study using the contact details below:

**Dr Eleanor Dommett**

Department of Psychology, Institute of Psychiatry, Psychology and Neuroscience,

2.13 Addison House,

Guy's Campus, Kings College London,

SE1 1UL

Telephone: 0207 848 6928

Email: Eleanor.Dommett@kcl.ac.uk

If this study has harmed you in any way or if you wish to make a complaint about the conduct of the study you can contact King's College London using the details below for further advice and information:

The Chair, Nursing and Midwifery Research Ethics Subcommittee

[**rec@kcl.ac.uk**](mailto:rec@kcl.ac.uk)

You can also contact SLaM PALS using the following details:

**SLaM PALS**

Freephone: 0800 731 2864 (Option 2)

Email: [pals@slam.nhs.uk](mailto:pals@slam.nhs.uk)

**Thank you for reading this information sheet and for considering taking part in this research.**